Remarks

Claims 1-26 were pending in the application, of which claims 1, 17 and 25 are the independent claims. Claims 1, 17 and 25 are amended herein. Claims 2 and 26 are cancelled without prejudice. No new Claims have been added. Accordingly, Claims 1 and 3-25 remain in the application. Reconsideration and further examination are respectfully requested.

No new matter is believed to have been introduced to the application by this amendment. The changes to the claims are fully supported by the original disclosure, including, for example, original paragraphs [0050], [0078], [0097], [0098] and [0099] and original claim 2.

Claim Rejections - 35 U.S.C. §101

Claims 25-26 were rejected under 35 U.S.C. §101 for allegedly not being tied to a machine nor executing a transformation.

While Applicant disagrees with the Examiner's rejection, to expedite prosecution of the present application, Applicant has amended Claim 25 to include a "computer implemented method" limitation in the preamble. Amended Claim 25 is believed to meet the requirements of 35 U.S.C. §101 at least because amended Claim 25 recites a "computer implemented method" wherein various steps are performed at a computer, thereby performing useful transformation of data and tying the claimed method to a machine.

Applicant respectfully requests reconsideration and withdrawal of the 35 U.S.C. §101 rejection of Claim 25.

With this paper, Applicant has cancelled Claim 26, rendering the 35 U.S.C. §101 rejection of Claim 26 moot.

Claim Rejections – 35 U.S.C. §103

Claims 1-7, 9-21 and 23-26 were rejected under 35 U.S.C. §103(a) as being unpatentable over Halvorson (US Patent No. 4847764) in view of Allen, III (US Patent No. 4731726, hereinafter "Allen"). Claims 8 and 22 were rejected under 35 U.S.C. §103(a) as being unpatentable over Halvorson in view of Allen and further in view of Kaufman et al. (US Patent. No. 5267174, hereinafter "Kaufman"). These rejections are hereby traversed and reconsideration and withdrawal thereof are respectfully requested.

Claim 1 relates to a patient care system, comprising a plurality of medication administration devices for delivering medication to a plurality of patients, a central processing unit (CPU) in communication with a subset of the plurality of medication administration devices and configured to monitor the subset of the plurality of medication administration devices and display results of the monitoring. The CPU is further in communication with at least one peripheral equipment comprising a barcode reader, an infusion pump or a monitor for monitoring a patient's vital signs. The CPU is configured to track a location of the at least one peripheral equipment in a hospital. The system further comprises a memory associated with each medication administration device for storing medication administration information associated with the medication delivered to each patient, the medication administration information including a plurality of medication administration parameters and a parameter value associated with each medication administration parameter, a central processor configured to receive medication administration information from each of the medication administration devices, a central computer display connected to the central processor and configured to display a color coded display of status and schedule information for all drug administrations to the plurality of patients, a database operatively connected to the central processor for storing medication

administration guidelines representing acceptable values for the medication administration parameters, and means for communicating medication administration information from each of the medication administration devices to the central processor. The central processor is further configured to compare the parameter values to the acceptable values for the parameters in the medication administration guidelines. The central processor is further configured to display a list of ongoing infusions to the plurality of patients. The central processor and the CPU are communicatively coupled via a local area network.

Claim 17 relates to a computer-implemented method for centralized monitoring of medication administration for a plurality of patients, comprising monitoring medication administration information associated with medication delivered to each patient, the medication administration information including a plurality of medication administration parameters and a parameter value associated with each medication administration parameter, storing a database of medication administration guidelines representing acceptable values for the medication administration parameters, communicating the medication administration information and the medication administration guidelines to a central location, comparing, on a computer at the central location, the parameter values to the acceptable values for the parameters in the medication administration guidelines, said acceptable values comprising a soft limit and a hard limit, operating a medication administration device by issuing an alarm if one of said parameter values contravenes its corresponding hard limit; and providing, using the computer at the central location, a visual indication on a computer display at the central location if one of the parameter values contravenes its corresponding soft limit in the medication administration guideline, and requiring an acknowledgment from a user before operating the medication administration device using a medical administration parameter contravening a corresponding soft limit.

Claim 25 relates to a computer implemented method of administering medication to a patient in a hospital. The method comprises: reviewing, at a pharmacy computer, a medication order prescribed by a physician, checking, at the pharmacy computer, the medication order for incompatibilities with the patient's record, transferring the medication order to a nursing station following the checking for incompatibilities, programming a clinical device connected to the patient and communicatively coupled with the pharmacy computer with medication delivery parameters, verifying, at the pharmacy computer, the medication delivery parameters, and if the verification passes, then administering the medication order to the patient using the clinical device according to the verified medication delivery parameters, and if the verification fails, then sounding an alarm at the pharmacy computer, allowing a user to correct or override, in real-time, the medication delivery parameters; and administering the medication order to the patient using the clinical device according to the corrected or overridden medical delivery parameters.

The cited references are not seen to teach at least "a CPU further in communication with at least one peripheral equipment comprising a barcode reader, an infusion pump or a monitor for monitoring a patient's vital signs, the CPU configured to track a location of the at least one peripheral equipment in a hospital," "a central computer display connected to the central processor and configured to display a color coded display of status and schedule information for all drug administrations to the plurality of patients," and that "the central processor is further configured to display a list of ongoing infusions to the plurality of patients," as recited in amended Claim 1, a method comprising "requiring an acknowledgment from a user before operating the medication administration device using a medical administration parameter contravening a corresponding soft limit," as recited in amended Claim 17 and a method comprising "allowing a user to correct or override, in real-time, the medication delivery

parameters; and administering the medication order to the patient using the clinical device according to the corrected or overridden medical delivery parameters," as recited in amended Claim 25 of the present application.

Turning now to the applied references, Halvorson discloses a system for controlling the dispensing and inventory of medications in a health care institution (technical field of the invention). In the Office Action, the Examiner alleges that at least Figure 1 and related text of Halvorson teaches "a CPU in communication with a subset of the plurality of medication administration devices and configured to monitor the subset of the plurality of medication administration devices and display results of the monitoring." In the relevant portion, Halvorson is seen to teach a computer 10 coupled to a dispensing station 32 with or without a dispenser 32, a system console 20, various consoles 20 and a physician database 21. However, Halvorson is not seen to show or teach connecting "the CPU to at least one peripheral equipment comprising a barcode reader, an infusion pump or a monitor for monitoring a patient's vital signs, the CPU configured to track a location of the at least one peripheral equipment in a hospital," as recited in amended Claim 1 of the present application. As explained at least at paragraphs [0050], [0058] and [0078] of the present application, such a configuration of the CPU facilitates real-time monitoring of peripheral devices and tracking locations of the peripheral devices in a medical facility so that the peripheral devices can be easily located by a nurse or a technician.

Furthermore, while Halvorson teaches displaying various medical parameters to a user, Halvorson is seen to be silent about using a color coded display of status and schedule information for all drug administrations to the plurality of patients, as recited in Claim 1 of the present application. As described in the present application, at least at paragraphs [0055] and

[0057], such color coding is useful to a medical practitioner in ensuring proper medication delivery to a patient.

Because the computer 20 of Halvorson is connected to medical *dispensing* devices (i.e., cabinets that hold medical drugs, as shown in FIG. 2 of Halvorson), but not to medical *administration* devices (e.g. infusion pumps), the computer 20 seems to be unaware of actual infusion using the dispensed medications. As a result, Halvorson is silent about teaching a central computer configured to display a list of <u>ongoing infusions</u> to a plurality of patients, as recited in amended Claim 1.

While Halvorson discloses certain limits on medication dispensing (e.g., limiting minimum and maximum times between dosages, number of days or maximum number of times of a dosage), at column 5, lines 27-29, Halvorson does not seem to teach two type of limits: a soft limit and a hard limit on medication parameters, as in amended Claim 17 of the present application. Having two different limits on medication delivery parameters advantageously balances between the need to stop medical fluid administration if treatment parameters are outside rules and protocols of a hospital, yet at the same time allow a medical professional to use professional judgment to override such disruptions, as appropriate. Furthermore, Halvorson teaches that medication dispensing contravening the limits are reported by producing a report, allowing a physician to renew medication orders (column 5, lines 29-34). In contrast, amended Claim 17 of the present application recites medication administering comprising "an acknowledgment from a user before operating the medication administration device using a medical administration parameter contravening a corresponding soft limit." In other words, while Halvorson requires a user to "renew" relevant medication parameters (e.g. a prescription), the present invention allows the use of existing medical parameters by medical personnel

acknowledging the use. As discussed at several places in the present application (e.g., paragraphs [0050] and [0064]), such a feedback method is advantageous in real-time monitoring of medication administration. Furthermore, because Halvorson requires off-line activity by a user, for example, renewal of a prescription by a doctor, Halvorson does not fairly teach "allowing a user to correct or override, <u>in real-time</u>, the medication delivery parameters; and administering the medication order to the patient using the clinical device according to the corrected or overridden medical delivery parameters," as recited in Claim 25 of the present application.

Turning now to Allen, this reference is not seen to remedy the deficiencies of Halvorson discussed above with respect to Claims 1, 17 and 25. Allen discloses a patient-operated glucose monitor and diabetes management system (title). The system comprises a monitor 10 coupled to a patient 114 for evaluating insulin behavioral data, in turn coupled to a computer 102 via a modem 104. Allen is seen to be silent about any location tracking of the peripheral equipment in a hospital, as recited in amended Claim 1 of the present application. Furthermore, Allen is seen to disclose operation of a single, home-based glucose monitor with a physician's computer. Allen also teaches that the monitor operates independent of any link to the computer 102. Therefore, Allen is not seen to teach a central processor that is "further configured to display a list of ongoing infusions to the plurality of patients," and a central computer display configured to display a color coded display of status and schedule information for all drug administrations to display a color coded display of status and schedule information for all drug administrations to a plurality of patients," as recited in amended Claim 1 of the present application.

Furthermore, while Allen teaches operation of a glucose monitor programmed with certain limits (e.g., blood sugar limits); such operation is based on pre-determined limits (e.g., column 18, line 2) and seems to be carried out without any provision for manual intervention or

acknowledgement. In particular, Allen does not seem to teach or show using "an acknowledgment from a user before operating the medication administration device using a medical administration parameter contravening a corresponding soft limit," as recited in Claim 17 of the present application. For the same reason, Allen does not seem to teach or show "allowing a user to correct or override, <u>in real-time</u>, the medication delivery parameters; and administering the medication order to the patient using the clinical device according to the corrected or overridden medical delivery parameters," as recited in Claim 25 of the present application.

Turning now to Kaufman, even if Kaufman were combined with Halvorson in the sense of "periodically comparing parameter values to the acceptable values for the parameters," as done by the Examiner, Kaufman is not seen to remedy the deficiencies of Halvorson and Allen discussed above. Kaufman discloses an interactive medication delivery device (abstract). While Kaufman discusses using "health parameters of a patient" at several places in the disclosure, Kaufman is silent about comparing the parameter values against any limits. In particular, Kaufman is silent about "comparing, on a computer at the central location, the parameter values to the acceptable values for the parameters in the medication administration guidelines, said acceptable values comprising a soft limit and a hard limit," as recited in Claims 1 and 17 of the present application. Furthermore, Kaufman is also silent about "allowing a user to correct or override, in real-time, the medication delivery parameters, and administering the medication order to the patient using the clinical device according to the corrected or overridden medical delivery parameters," as recited in amended Claim 25 of the present application.

Therefore, Halvorson, Kaufman and Allen, either separately or in combination, fail to teach or show a patient care system as claimed in claims 1, 17 and 25 of the present application.

Based on the above discussion, it is respectfully submitted that amended claims 1, 17 and 25 are in condition for allowance and the rejection under 35 U.S.C. §103 should be reversed.

Claims 2-16 depend from Claim 1 and are believed to be in condition for allowance at least for the reasons presented with respect to Claim 1. Reconsideration and withdrawal of the 35 U.S.C. §103 rejection of Claims 2-16 is respectfully requested.

Claims 18-23 depend from Claim 17 and are believed to be in condition for allowance at least for the reasons presented with respect to Claim 17. Reconsideration and withdrawal of the 35 U.S.C. §103 rejection of Claims 18-23 is respectfully requested.

Claim 8 depends from Claim 1 and is believed to be in condition for allowance at least for the reasons presented with respect to Claim 1. Reconsideration and withdrawal of the 35 U.S.C. §103 rejection of Claim 8 is respectfully requested.

Claim 22 depends from Claim 17 and is believed to be in condition for allowance at least for the reasons presented with respect to Claim 17. Reconsideration and withdrawal of the 35 U.S.C. §103 rejection of Claim 22 is respectfully requested.

Claim 26 has been cancelled, rendering the 35 U.S.C. §103 rejection of Claim 26 moot.

In light of the amendments and remarks above, this application should be considered in condition for allowance and the case passed to issue. If you have any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated to expedite the prosecution of the application.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,
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